



**WASHINGTON STATE PATROL**

**DNA ANALYSIS QUALITY ASSURANCE MANUAL**

**CRIME LABORATORY DIVISION**

**December 2017**

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## GOALS AND OBJECTIVES

### GOALS OF THE WSP DNA AND CODIS LABORATORIES:

- Provide state and local law enforcement agencies laboratory services for DNA typing of selected biological materials associated with official criminal investigations.
- Perform DNA typing on reference samples submitted from individuals convicted of qualifying crimes defined under RCW 43.43.752 through 43.43.759 (Convicted Offender Program), maintain the computerized data bank of the DNA typing results from these samples, and conduct searches of the data bank to assist law enforcement agencies in identifying possible suspects from DNA typing results obtained from samples recovered from a crime scene or related to missing persons/unidentified human remains. To provide post-conviction DNA testing as defined under RCW 10.73.170.
- Ensure the quality, integrity, and scientific accuracy of the DNA typing data through the implementation of a detailed DNA Quality Assurance (QA) Program.

### PROGRAM DEVELOPMENT

The DNA QA Program was developed by and is updated through input from the DNA analysts, the DNA supervisors and the DNA Technical Leader. Any changes to the DNA QA Program will be applied throughout the system and will be approved by the DNA Technical Leader. Ultimate responsibility for all quality assurance-related functions resides with the Standards and Accountability Manager, who is also the Quality Assurance Manager.

The Quality Assurance Standards approved by the FBI Director and the FBI DNA Quality Assurance Audit Document will provide the basis for the Washington State Patrol Crime Laboratory's DNA QA Program. Any revisions to the forensic or database laboratory standards will be reviewed for incorporation if applicable into the Washington State Patrol Crime Laboratory's DNA QA Program.

### PROGRAM SCOPE

The DNA QA Program described in this manual is intended to support the DNA typing of biological materials, to ensure that the DNA typing procedure is operating within established performance criteria, and to ensure that the quality and integrity of the data is maintained and is scientifically sound.

### PROGRAM OBJECTIVES

#### Objectives of the QA Program:

- Ensure uniformity and accountability in records and analysis techniques.
- Monitor analysis methods by using known standards and evaluate test results based on the performance of the known standards.
- Ensure the accuracy of the data generated.

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- Document corrective actions taken.
- Monitor personnel and equipment performance.
- Terminate nonconforming materials or work.
- Test system with NIST traceable DNA standard reference material at least annually.
- Ensure the proper preparation and documentation of reagents used.
- Require testing of critical reagents prior to their use in casework.
- Ensure use of documented and valid materials and procedures.
- Provide feedback to management on quality assurance performance.
- Ensure that DNA typing results are technically sound and legally defensible.
- Provide guidelines and expectations to employees.
- Ensure that personnel performing this testing have the appropriate level of training and education.
- Ensure that analysts are competent in performing the testing and interpreting of test results through a series of proficiency tests.
- Provide for a safe work place.
- Provide for competent internal and external audits to check that the operating policies and procedures are being followed and that they adequately meet national quality assurance standards.

## ORGANIZATION AND MANAGEMENT

### ORGANIZATION AND MANAGEMENT STRUCTURE

See the Washington State Patrol (WSP) Crime Laboratory Division (CLD) Quality/Operations Manual (QOM) for a full description of the Organization and Management Structure of the WSP CLD.

### FUNCTIONAL RESPONSIBILITIES

Each casework DNA section and CODIS consists of DNA analysts (Forensic Scientists, class series 1-3) and at least one supervising DNA analyst (Forensic Scientist 5). A casework DNA section may have serology screening analysts that can work independently to find and identify biological evidence and can prepare cell pellets for DNA analysis. There may also be a Laboratory Technician 2 who performs, in the section, laboratory duties exclusive of analytical techniques on forensic or database samples. The supervisors will assign the responsibility of monitoring and documenting the quality control measures provided for in this DNA QA manual.

Each casework DNA laboratory has an individual assigned as a Technical Lead DNA analyst (Forensic Scientist 4) who is accountable for the quality of the casework/CO sample work product, for compliance with all applicable accreditation and audit criteria, compliance documentation, validation of new technology and methods, validation of new personnel beginning casework/CO sample analysis, and investigation of casework errors. The Technical Leads do not act alone, but with consultations of the DNA Functional Area (DNA FA), the supervisors, and the DNA Technical Leader. There is one Tech Lead position assigned to Standards and Accountability providing assistance to the DNA Technical Leader. The Forensic Scientist 5 CODIS is accountable for (including the delegation of) the aforementioned Technical Lead responsibilities.

Each casework DNA section has one DNA analyst who also functions as the Local CODIS administrator (LDIS Administrator) who is responsible for the operations of the CODIS system within their laboratory (reference [Convicted Offender/CODIS Program Standard Operating Procedures](#)).

The DNA Technical Leader manages the technical operations of the DNA FA within the Crime Laboratory Division. As such, this individual will be directly responsible for quality issues involving the DNA FA and will work with the LA and QP Managers on all quality matters. The DNA Technical Leader has technical oversight of the CODIS program and plans and coordinates DNA audits.

The CODIS Manager manages and operates the CODIS Laboratory and is responsible for CODIS-related issues throughout the division including the security of the DNA profiles stored in CODIS. The CODIS Manager or designee reports to the DNA Technical Leader for CODIS technical/analytical related issues.

If the Management Liaison is not the DNA Technical Leader, the intent in functional area representation is to have the ML specialize more in non-technical matters and the DNA TL specialize more in technical matters with some overlap, consultation and coordination.

### LEVELS OF AUTHORITY

Individuals in a DNA section are empowered by the section supervisor to carry out QA/QC responsibilities and to act in his/her place. The supervisor is to be informed of any action taken as soon as practical. This means, for example, that a DNA analyst may reject any reagent or material that fails to meet

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specifications. Should an analyst feel that a technical problem is not being adequately addressed within his/her section, that person has the authority to go directly to the DNA Technical Leader.

Technical Leads (FS4s, or the CODIS FS5) have the responsibility to recommend the termination of testing in DNA in the event of a technical problem with a technical procedure, instrumentation, or equipment. Communication of such action must follow the appropriate chain of command.

The section supervisors have the overall responsibility of the DNA Unit and can mediate discrepancies that arise between the analyst and the reviewer in peer review. They are designated by the DNA Technical Leader with the authority to approve acceptable minor deviations from STR interpretation guidelines and protocols. Technical Leads (FS4s) are designated by their section supervisor with the authority to approve acceptable minor deviations from STR interpretation guidelines and protocols.

The CODIS Manager has the authority to terminate an analyst's or laboratory's participation in CODIS in the event of a problem until the reliability and security of the computer data can be assured in the event an issue with the data is identified. The DNA Technical Leader and the Quality Assurance Manager will be notified as soon as practical.

LDIS Administrators have the authority to terminate an analyst's or their laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified. Any such action shall require notification to the CODIS Manager, DNA Technical Leader and Quality Assurance Manager as soon as practical.

The DNA Technical Leader has the authority to initiate, suspend and resume DNA analytical operations for the laboratory or an individual.

All proposed changes to the quality systems, and all reports of quality variances, will be reported to the CLD Standards and Accountability Section per the CLD Quality/Operations Manual.

If the Management Liaison is not the DNA Technical Leader, refer to the CLD Quality/Operations Manual (Section 4) for a role description.

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## PERSONNEL QUALIFICATIONS AND TRAINING

All persons involved in the actual recovery, evaluation, analysis, and interpretation of DNA evidence shall have a background and training appropriate to the duties assigned.

### JOB DESCRIPTION

Job descriptions for personnel within the DNA FA can be found in the CLD Quality/Operations Manual.

### EDUCATION AND GENERAL REQUIREMENTS

All forensic scientists in the Washington State Patrol Crime Laboratory DNA FA must possess a minimum of a Bachelor's degree in a biology-, chemistry-, or forensic science- related area

- The DNA Technical Leader must have, at minimum, a Masters' degree in biology-, chemistry- or forensic science- related area and successfully completed 12 semester or equivalent credit hours from a combination of undergraduate and graduate course work covering the following subject areas: biochemistry, genetics, molecular biology, and statistics or population genetics, and a minimum of three years of experience as a forensic DNA analyst. The DNA Technical Leader shall have previously completed or successfully complete the FBI sponsored auditor training within one year of appointment.
- The CODIS Manager shall have, at a minimum, the general requirements listed above and shall have successfully completed course work (graduate or undergraduate level) covering the following subject areas: biochemistry, genetics, molecular biology; and course work and/or training in statistics and/or population genetics as it applies to forensic DNA analysis. The CODIS Manager shall have a minimum of three years' experience as a forensic DNA analyst with documented mixture interpretation training. It is also desirable that the CODIS Manager have a working knowledge of computers, networks, and computer database management.
- A DNA analyst (forensic scientist) shall have, at a minimum, the general requirements listed above and shall have successfully completed course work (graduate or undergraduate level) covering the following subject areas: biochemistry, genetics, molecular biology; and course work and/or training in statistics and/or population genetics as it applies to forensic DNA analysis. Analysts are subject to the forensic scientist class series as outlined in the CLD Quality/Operations Manual.
- A DNA supervisor (Supervising Forensic Scientist) must meet the Washington State Patrol Crime Laboratory requirements for a Forensic Scientist 5 and have a minimum of two years of experience in forensic biology as a Forensic Scientist 3 or five years full-time paid technical experience in a forensic laboratory which includes two years performing analyses of physical evidence and testifying as an expert witness in courts of law.
- A DNA Technical Lead must meet the Washington State Patrol Crime Laboratory requirements for a Forensic Scientist 4.



- The Laboratory Technician 2 must have, at a minimum, an associates' degree in biology, chemistry, lab technology, microbiology, or molecular biology. The lab tech 2 must also have a working knowledge of basic laboratory tools such as pipettes and balances.

## TRAINING AND QUALIFICATIONS

All forensic scientists will have completed training in the fundamentals of forensic science, including training in the handling of biological evidence. The [Biochemical Analysis Training Program](#) and [STR Training Program](#) manuals outline the WSP CLD training program for the qualification of all analysts in the DNA functional area. Training may be accomplished in-house or with a combination of in-house work and outsourcing to outside vendors. Prior to independent casework, the analyst should perform supervised casework for a period of time to be determined by the supervisor (see CLD Quality/Operations Manual Section 5) with an experienced, qualified Forensic Scientist.

Before a Forensic Scientist is qualified to examine and identify biological evidence for DNA casework, the scientist must have demonstrated, either through successful completion of formal course work or through in-house training, knowledge in the following areas:

- Documentation and reporting procedures.
- Safe laboratory practices.
- Serology screening methodologies for various body fluids and mixtures of body fluids.
- DNA Quality Control and Quality Assurance systems and methods.
- Equipment operation, calibration and maintenance.
- Courtroom demeanor and moot court testimony (prior to testifying in court).

In addition, the forensic scientist must complete well-documented sets of serology screening training samples.

Before a Forensic Scientist is qualified to analyze DNA casework, the scientist must have demonstrated, either through successful completion of formal course work or through in-house training, knowledge in the following areas:

- Documentation and reporting procedures.
- Safe laboratory practices.
- DNA STR methodology and biochemical analysis methodologies.
- DNA Quality Control and Quality Assurance systems and methods.
- Equipment operation, calibration and maintenance.
- Quantitative and qualitative evaluation of DNA test results.
- DNA case acceptance policies.
- Interpretation of electropherograms.
- Mixture interpretation training
- Statistical interpretation of STR results.
- DNA trouble-shooting.
- Courtroom demeanor and moot court testimony.

In addition, the forensic scientist must complete well-documented sets of DNA training samples.

Before a Forensic Scientist is qualified to analyze convicted offender samples using STR analysis, the scientist must have demonstrated, either through successful completion of formal course work or through in house training, knowledge in the following areas:

- Familiarity with convicted offender statutes.
- Processing, documentation and reporting procedures for convicted offender samples.
- Safe laboratory practices.
- DNA STR methodology.
- DNA Quality Control and Quality Assurance systems and methods.
- Equipment operation, calibration and maintenance.
- Quantitative and qualitative evaluation of DNA test results.
- Interpretation of electropherograms.
- DNA trouble-shooting.
- Statistical interpretation applicable to a CODIS database laboratory

In addition, the forensic scientist must complete well-documented sets of DNA training samples.

When an experienced Forensic Scientist is hired, the DNA Technical Leader shall be responsible for assessing their previous training and ensuring it is adequate and documented. Modification(s) to the training program may be appropriate and shall be documented by the DNA Technical Leader.

In addition, the forensic scientist must complete well-documented sets of serology screening samples and DNA training samples.

Before a laboratory technician is qualified to prepare reagents, and perform QC checks on reagents, instruments, and DNA kits, the technician must complete training and demonstrate knowledge and competence in the following areas:

- Safe laboratory practices
- Documentation procedures
- Relevant sections of the Biochemical Analysis Training Manual
- Relevant sections of the STR Training Manual
- DNA Quality Control and Quality Assurance systems and methods
- Equipment operation, calibration, and maintenance

In addition, the lab technician must complete well-documented sets of DNA training samples.

Upon completion of an approved training program, the Laboratory Manager and DNA Technical Leader will authorize the lab tech to perform reagent preparation and QC checks on reagents, instruments, and DNA kits.

The DNA Laboratory Technician will not process evidence or perform casework, and is designated as Laboratory Support Staff for the purposes of the FBI DNA Quality Assurance Standards.

## EXPERIENCE

Prior to any DNA typing and reporting on convicted offender or casework samples, the DNA analyst must have a minimum of six months of forensic DNA laboratory experience. Prior to any independent serology screening and reporting on casework samples, the Serology Screener must have a minimum of 3 months of forensic serology laboratory experience.

The casework DNA analyst or Serology Screener shall complete the analysis of a range of samples routinely encountered in forensic casework prior to independent work using DNA technology and shall successfully complete a competency test before beginning independent analysis.

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The CODIS DNA analyst shall complete the analysis of a range of samples routinely encountered in the convicted offender program prior to independent work using DNA technology and shall successfully complete a competency test before beginning independent analysis.

## **CONTINUING EDUCATION**

DNA analysts, DNA Tech Leads, DNA Supervisors, the DNA Technical Leader, and the CODIS Manager must stay abreast of developments within the field by reading current scientific literature and by annual attendance at seminars, college courses, professional meetings, or documented training sessions/classes in relevant subject areas at least once each calendar year. The review of scientific literature can be documented by recording DNA Lab journal club attendance and articles discussed or alternatively initialing copies of relevant DNA articles read. A minimum of eight cumulative hours of continuing education are required annually and shall be documented. Management must provide analysts with an opportunity to comply with the above.

## **TRAINING RECORDS**

Supervisors have the responsibility of maintaining and routing documentation of all training received for each analyst. The Standards and Accountability Section will keep a record of completed training and the QP Manager will forward the record to the WSP Training Division to be added to the employee training records.

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## FACILITIES

Each laboratory will be secured and have access limited to personnel and escorted/observed visitors. Each laboratory will have an evidence storage vault, locked refrigerators and/or freezers, and personal evidence lockers for the secure storage of evidence pending or in the process of examination. The CLD Quality/Operations Manual outlines the process and procedures regarding security of the laboratory and evidence.

The DNA section of each laboratory shall have a room separate from the examination area in which amplified DNA product (including real-time PCR) is generated, processed and maintained. Additionally, evidence examinations, DNA extractions, and PCR setup shall occur in separate spaces, or at separate times.

When robotic workstations are used to carry out DNA extraction, quantitation, PCR setup, and/or amplification, a single room may be used provided that appropriate validation has been performed and documented. If the robot performs analysis through amplification, the robot shall be housed in a separate room from that used for initial evidence examinations.

Each DNA laboratory shall have and follow written procedures for cleaning and decontaminating facilities and equipment. The procedures for facilities cleaning shall be maintained in a DNA Lab Cleaning Log for the particular laboratory. The procedures for equipment maintenance including cleaning shall be maintained in the appropriate STR Analysis Procedures Manuals (Crime Laboratory and CODIS Laboratory).

## **CASEWORK EVIDENCE AND SAMPLE CONTROL**

### **RECEIPT, STORAGE, AND HANDLING OF EVIDENCE SUBMITTED TO THE CRIME LABORATORY**

Evidence items will be received, stored and handled in such a manner to ensure integrity by protecting from loss, cross contamination or deleterious change. The guidelines for evidence receipt, storage and handling are outlined in the WSP CLD Quality/Operations Manual.

### **SAMPLE LABELING AND DOCUMENTATION**

Each DNA test sample will be labeled with a unique identifier (i.e., laboratory number and, if appropriate, an item number and/or item description). DNA samples are not considered evidence. The guidelines for handling samples are outlined in the WSP CLD Quality/Operations Manual.

### **EVIDENCE AND TEST SAMPLE HANDLING**

Evidence items and test samples shall be handled in a manner to prevent loss, alteration, contamination, or mixing. Analysts will wear gloves while handling evidence and test samples both to preserve the integrity of the evidence and for personal protection. When working with limited evidence or low level DNA samples (such as handler/touch/cellular cases), disposable sleeves and a mask or plexiglass shield must be employed.

Analysts will use disposable plugged pipette tips, discarding tips after each use involving possible contact with DNA sample or controls; not have more than one sample open at a time; and use quality-controlled reagents when necessary. All items prior to coming into contact with sample must be sufficiently cleaned to prevent DNA cross contamination. For example sample-handling tools (such as scissors or scalpels) must be cleaned between the preparations of each sample. Examples of cleaning techniques include but are not limited to using autoclaved or physically cleaned rinsed/wiped or physically cleaned rinsed/wiped and Sterigard 250 treated sample-handling tools.

Evidence samples shall be prepared separately (time and/or space) from the known reference samples.

DNA samples will be stored under conditions to maintain shelf-life and reduce or prevent the degradation of DNA (refrigeration or freezing for liquid extracts). Refer to the Analytical Procedures section of this manual for guidelines regarding inadvertent deleterious changes (loss, mixing, contamination, etc.) to DNA extracts.

### **CONSUMPTION OF DNA EVIDENCE AND LIMITED SAMPLES**

Forensic Scientists will make every reasonable attempt to conserve sufficient DNA evidence or sample for retesting, but may need to use it all in their analysis depending on the amount of biological material available.

The determination of whether or not consumption of a visible sample is appropriate is generally based on the scientist's assessment of the staining observed or an estimate of the number of spermatozoa recovered.

For evidence items that cannot be visually assessed for quantity of biological material (i.e. cells left on a surface from touching or other contact), assessment for consumption will be at the point of DNA sample quantification.

For re-testing the sample or DNA extract, the forensic scientist will preserve enough of the sample or DNA extract for a reasonable chance of replicating the original test result. As a general guide, the amount

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preserved may be approximately half or more of the sample or DNA extract (i.e., one of two swabs, approximately half or more of the swab, approximately half or more of the area sampled or approximately half or more of the total DNA extracted). The forensic scientist will exercise reasonable care in determining the amount of sample or DNA extract preserved for replicating the original test result (i.e., same or more genetic information).

Unrestricted consumption of the sample or DNA extract may proceed after receipt of a signed Authorization for Consumption form or authorization for a consumption in a note, memo, letter or email.

If written approval for unrestricted consumption has not been obtained, any outside expert retained/hired to observe testing must follow the procedure for Observation by Outside Experts outlined in the CLD Quality/Operations Manual [Section 21].

If applicable, discuss with the prosecutor, as part of the consumption process agreement, that, if during the analysis being observed by an outside expert, the quantification of the consumed evidence item shows sufficient DNA to allow for re-testing, the DNA analyst can stop the observation of the testing at that point.

The guidelines governing observation by outside experts are outlined in the WSP CLD Quality/Operations Manual.

## **STORAGE, DISPOSITION, AND DESTRUCTION OF EVIDENCE AND WORK PRODUCT**

Any item (Convicted Offender samples excluded) submitted for analysis to the crime laboratory by a law enforcement agency is considered evidence. Forensic analysis of evidence items will result in work products. This may include microscope slides, DNA extracts, DNA amplicons, bloodstain cards and stain excision cutting, etc. Work products as a result of crime lab analysis are not considered evidence.

All evidence items for DNA testing will be stored in secure areas (personal lockers, locked refrigerators/freezers) until returned to the submitting agency. The CLD Quality/Operations Manual addresses general issues for evidence items. Historical work product such as DNA extracts, bloodstain cards (e.g. stains made from reference samples), stain excision cuttings, microscope slides, etc. may be retained for possible cold case and post-conviction DNA investigations. To maintain the integrity of some DNA analysis work products such as bloodstain cards and stain cuttings, it may be necessary to use the laboratory's evidence vault for storage due to suitable space limitations.

DNA extract work product will be stored as specified in the Casework STR Analysis Procedures manual. Prior to July 2010, any extracted DNA not utilized in analysis was typically retained by the laboratory. If not, the disposition was recorded in the case notes. After July 2010, any extracted DNA from evidence items not utilized during casework analysis was returned to the submitting agency upon completion of the case. After July 24, 2015, all DNA work product produced during sample analysis, including remaining DNA extracts from evidence (excluding reference samples), microscope slides, and sample cuttings or cellular material not subjected to DNA extraction, will be returned to the submitting law enforcement agency as a new item of evidence. The disposition for all work product will be recorded in the case notes. Reagent blanks from extractions where there is no remaining DNA may be discarded. All amplified DNA shall be discarded. Extracted DNA from reference items shall be discarded unless the reference DNA extract is being preserved for Y-STR testing. A reference DNA extract may be retained following Y-STR testing if that extract has been previously included in the new item of evidence created for the DNA work product.

The case notes and report will specify the new item which contains the returned DNA extracts and/or other work product. Additionally, where possible, evidence packaging will be labeled (i.e. stickers or other method) to indicate that DNA work product is enclosed.

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## CONVICTED OFFENDER SAMPLE CONTROL

### RECEIPT, STORAGE, AND HANDLING OF OFFENDER SAMPLES SUBMITTED TO THE CODIS LABORATORY

Washington State Patrol CODIS Laboratory guidelines for the receipt, storage, and handling of samples submitted to the CODIS Laboratory are documented in the [WSP CLD CODIS Laboratory STR Procedures Manual](#).

### SAMPLE LABELING AND DOCUMENTATION

Each sample will be labeled with a unique identifier (i.e., laboratory number). For more information see the [WSP CLD CODIS Laboratory STR Procedures Manual](#).

### SPECIMEN HANDLING

Samples will be handled in a manner to prevent loss, alteration, contamination, or mixing. Analysts will wear gloves while handling samples both to protect the samples from bacterial or endonuclease attack and for personal protection. When working with low DNA level samples, disposable sleeves and a mask or plexiglass shield must be employed. Analysts will also discard disposable pipette tips after each use, and use quality controlled solutions and reagents when necessary. Any sample-handling tools used (such as scissors or forceps) will be rinsed and wiped off between the preparation of each sample.

Samples will be stored under conditions to maintain shelf-life and reduce or prevent the degradation of DNA (refrigeration or freezing for liquid extracts). Refer to the Non-Conforming Work section of this manual for guidelines regarding inadvertent deleterious changes (loss, mixing, contamination, etc.) to DNA extracts.

### DESTRUCTION OF DNA

All extracted and amplified convicted offender DNA will be destroyed upon completion of typing.

# METHODS VALIDATION

See the WSP CLD Quality/Operations Manual for a full description of procedures for Methods Validation.



## ANALYTICAL PROCEDURES

Standard operating procedures are followed for reagent preparation, processing of convicted offender samples, sample extraction and analysis, controls and equipment maintenance. These procedures are documented in the WSP Crime Laboratory STR Analysis Procedures Manual and WSP CODIS Laboratory STR Analysis Procedures Manual.

### DEFINITIONS

Chemicals – substances with a distinct molecular composition (e.g. ethanol, sodium chloride).

Reagents – substances prepared from chemicals or other reagents, or commercially available kits used in laboratory analysis that might not be considered standalone chemicals (e.g. TE, amplification kits).

### PREPARATION OF REAGENTS

Reagents will be prepared according to the instructions in the appropriate STR Analysis Procedures Manuals. The quantities and lot numbers of the materials used to prepare the reagents will be recorded in the laboratory's reagent preparation log book. Each batch of reagent prepared will be uniquely identified and recorded in the laboratory's reagent log book.

### LABELING OF REAGENTS USED FOR DNA TESTING

All in-house prepared reagents will be labeled with the following:

- The identity of the reagent.
- The date of preparation.
- The batch of the reagent.
- The expiration date.
- The initials of the individual preparing the reagent.

At a minimum, solutions on the bench, referred to as "working solutions," need to have the reagent name, the batch identifier, and expiration date on the label.

Commercially prepared reagents will be labeled with the following:

- The identity of the reagent.
- The expiration date, if one is provided by the manufacturer or determined by the laboratory.

Additional information on reagents can be found in the CLD Quality/Operations Manual Section 11 Traceability and Quality Control of Reagents. Refer to the WSP Safety and Wellness Manual Chapter 13 – Hazardous Chemical Communication Plan and 4.0 Acquisition and Storage of Chemicals in the CLD Safety Manual for information on MSDS labels and storage, respectively.

### CRITICAL REAGENTS

A list of critical reagents can be found in the WSP Crime Laboratory STR Analysis Procedures Manual and WSP CODIS Laboratory STR Analysis Procedures Manual. These reagents will be evaluated prior to their use.

## STANDARDS AND CONTROLS

All controls, internal lane standards and allelic ladders required for a given procedure will be run and checked to verify that the expected results were obtained. Further details are described in the appropriate STR Analysis Procedures manual sections.

## COMPARISON TO KNOWN STANDARDS

Once a year, each laboratory conducting DNA testing will type a minimum of a NIST DNA standard reference material, or standards traceable to a NIST standard, using the DNA typing technology and methodology in current use. The results of the testing will be documented and reported to the DNA Technical Leader. The DNA Technical Leader will check the genotypes for concordance. Any discrepancy between the laboratory's results and the published NIST standards or traceable standards profiles will be investigated and a root cause determined. If a serious finding in the DNA analysis is found, all typing will stop in that laboratory until the problem is corrected. All previous records will be examined back to the time it can be ascertained the error was not occurring. Appropriate actions regarding nonconforming work will be followed as outlined in the CLD Quality/Operations Manual.

If a new method is introduced or the existing method modified substantially, it shall not be utilized for casework or convicted offender testing until it has been tested using a NIST DNA standard or standard traceable to NIST standards and the appropriate values are obtained.

## GUIDELINES FOR THE PROPER RECORDING OF ALL ANALYTICAL DATA

The following information will be recorded in the permanent case file of every case submitted for DNA analysis and for each set of convicted offender samples typed:

- Request for Laboratory Examination (RFLE) Form for casework or a list of samples in the set for convicted offender samples.
- For casework, documentation of examination.
- Worksheets filled out appropriately to document the flow of the sample, including a sample description, extraction, quantitation, amplification, and capillary electrophoresis (CE) analysis. The appropriate reagent information for all reagents used will also be included, such as testing dates, lot numbers, etc. to allow for traceability of materials used in analysis.
- Results of the estimation of the quantity of human DNA recovered (unless samples are processed by direct amplification).
- Analytical data (stored electronically) which includes as appropriate, digital photographs of evidence, any robot templates, 7000/7500 SDS file(s), the normalization file, GeneMapper® ID files and projects, the raw data generated, appropriate matrices, size standard(s), allele table(s) (if desired) and CODIS tables (if warranted).
- Additionally, it will be verified and recorded that all controls run with the samples gave expected results.
  - Additional data to be recorded with criminal cases:

- Any population frequency calculations and/or data sheets.
- Any appropriate CODIS search/upload/match paperwork.
- A draft of the laboratory report bearing the technical reviewer's initials and the date of review on each page.
- The final laboratory report.

All case files and convicted offender samples will be reviewed by at least one other DNA analyst. An approved peer review checklist will be used to facilitate the review process. This must be retained in the case file for casework but can be retained in the case record for CODIS. Following the checklist will ensure adequate review of results at every step of analysis.

### **DATA HANDLING, STORAGE, AND RETRIEVAL**

All casework documentation will be maintained according to laboratory policy as outlined in the WSP CLD Quality/Operations Manual.

Electronic data will be stored as follows:

- For casework electronic data:
  - All original instrument data (run folders generated by the CEs or SDS files generated by the 7000/7500) will be backed up from the appropriate instrument computer hard drives to a Data Repository (DR) hard drive. At least once per quarter, the instrument data which has been backed up to the DR will be copied to removable media (e.g. CDR, DVDR or equivalent technology) and transferred to an offsite regional WSP Crime Laboratory or separate secure location.
  - Completed casework files will be placed in a Completed Cases (or equivalent) folder on the DR. Casework in this folder will be backed up at least quarterly (or more often depending on the number and size of the completed cases) using the same methods as outlined above.
  - When possible, the backing up of data from instruments and casework files should be completed using the highest quality removable media available, and should be stored in a manner to prevent data loss from that removable media.
- Reviewed offender sets, hit confirmations, and elimination sample sets will be backed up every three months. Electronic robot maintenance file records, proficiencies, and QC records will be backed up at least annually. The backup will be stored at a separate, secure location.
- CODIS data will be entered into and stored in the CODIS system according to [CODIS procedures and protocols](#). Data will be entered into the CODIS system from reviewed case files and reviewed offender sets as soon as conveniently possible.
- Crime Laboratory validation studies, performance testing results and population study work results and write-ups will be retained in the DNA section of each laboratory conducting DNA typing or in the CODIS Laboratory. After the initial creation of the work results and write-ups, it will be the responsibility of the DNA Technical Leader to decide what is added to or deleted

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from these files. The DNA/CODIS supervisor or designee will have the responsibility of ensuring that the material is added to or removed from all the files in their laboratory.

The Standards and Accountability Section is responsible for maintaining historical files containing all outdated analytical testing methods, procedures, and operating guidelines formerly used in the STR testing program.

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## EQUIPMENT CALIBRATION AND MAINTENANCE

An inventory of all critical equipment used in DNA testing will be maintained according to laboratory policy as outlined in the CLD Quality/Operations Manual. Instruments or equipment that require calibration or performance testing prior to use and periodically thereafter are critical as they may affect DNA testing.

New analytical instruments, or instruments which have undergone repair/maintenance, will be performance tested before use in casework or convicted offender sample analysis.

Any time a piece of equipment requires service or maintenance, that fact will be documented on the appropriate service form. Instruments which are on routine service contracts with the manufacturer will have routine service calls documented. All documentation of service, routine or otherwise, will be maintained in the appropriate instrument maintenance log book.

For equipment requiring calibration (such as pipettes, CEs, thermal cyclers, and their thermocouple probes), the calibration schedule can be found in the WSP Crime Laboratory STR Analysis Procedures Manual or CODIS Laboratory STR Analysis Procedures Manual. This calibration will be done using appropriate certified standards and will be documented in the appropriate equipment/instrument log book. A written procedure or set of instructions will be available for calibration of more complex instruments.

Some instruments will be calibrated routinely by certified external agencies (e.g., NIST traceable thermometers, balances, pipettes).

The Calibration of Instruments section of the WSP CLD STR Analysis Procedures Manual and the WSP CODIS Laboratory STR Analysis Procedures Manual outlines the performing of this quality assurance function.

The equipment/instrument maintenance procedure will clearly define the calibration source to be used and the frequency of calibration.

Each DNA section should establish acceptable temperature ranges for their temperature controlled equipment. Temperature checks are done each working day as specified in the Calibration of Instruments section of the WSP CLD STR Analysis Procedures Manual and the WSP CODIS Laboratory STR Analysis procedures Manual. The acceptable temperature range for passing the checks can be established by reviewing the history of temperature ranges where the functional performance of the equipment was acceptable. These ranges should be stored in the same binder as the Temperature Control Record Log form.

Refer to the WSP CLD Quality/Operations Manual (Section 11-Traceability and Quality Control) for information on microscope care and maintenance plan.

## REPORTS AND THE RELEASE OF INFORMATION

Issues regarding procedures for the release of case file information and reports are addressed in the CLD Quality/Operations Manual.

### REPORTS

Any analytical results released from the laboratory will be contained in a formal written report, and these reports will be prepared in accordance with existing Crime Laboratory Division policy. Prior to issuance of the report, the DNA analyst assigned to the case will have all data and conclusions independently reviewed by a second DNA analyst. This technical review will be documented in the case file.

The following information will be included in all reports:

- Case identifier
- Description of evidence examined
- A statement addressing non-examined items
- A description of methodology
- Amplification kit used or loci tested (where appropriate)
- Results and conclusions
- Quantitative or qualitative interpretation statement
- Disposition of evidence
- Date issued
- A signature and title of the person(s) accepting responsibility for the content of the report

### DISCOVERY AND PUBLIC DISCLOSURE

The DNA analyst will notify their supervisor when a discovery or public disclosure request is received. If appropriate, the supervisor may notify the laboratory manager and/or DNA technical leader (e.g. for excessive requests, requests for staff DNA profiles).

Discovery requests are usually received from the prosecutor's office. Discovery requests received from the prosecutor can be handled by the assigned scientist by providing the requested documents. If the request requires redaction or OPS or HRD records, the Public Disclosure Tracking Coordinator (PDTC) shall be notified and coordinate release of the records.

The Public Disclosure Tracking Coordinator (PDTC) shall be notified and coordinate release of records for all public disclosure requests, discovery requests received directly from the defense, subpoenas duces tecum, and any discovery request requiring redaction or records maintained by OPS or HRD (regardless of the requestor).

### If requested, these items can be provided via discovery request(s):

Note: The items listed below are not all-inclusive.

- Copy(ies) of the case file including electronic data CD (Note: See additional information below for case files with "no match" candidate paperwork or staff/elimination DNA profiles)
- Evidence Chain of Custody
- Proficiency test evaluation forms for up to two years
- Reporting DNA scientist and technical reviewer CV's
- Laboratory accreditation certificate and scope of testing
- Summary audit reports
- Current CLD manuals are available on-line at:  
[http://www.wsp.wa.gov/forensics/crimelab\\_docs.php](http://www.wsp.wa.gov/forensics/crimelab_docs.php). Archived versions of CLD manuals are on the FLSB Portal and may be provided on a CD

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- Manufacturer product inserts: scan/photocopy insert referencing the lot number of the kit used
- Copies of internal validation (summaries only).

**If requested, these items are made available for on-site (in lab) inspection:**

Pertinent pages viewed at the lab may be digitally scanned or copied by the reviewer if they provide their own virus free equipment (e.g. scanner/copier, thumb drive or hard drive). If the request is unduly burdensome, the analyst's supervisor and the prosecutor will be contacted.

- Original case file can be viewed with the exception of any "no match" candidate match paperwork. Documentation associated with an elimination DNA profile may only be viewed if a court order providing protection of the elimination DNA profile and/or name has been received.
- Quality Assurance Records: Quality variance logs, contamination logs, corrective actions, and detailed audit documentation and responses. The specific area of interest shall be requested in writing. Only entries in the log(s) dating from three months before the date of testing of the samples to three months after may be viewed.
- WSP Validation notes, electronic data, and data analysis tables
- DNA analyst training records
- Proficiency test files, electronic data and answer sheets
- Instrument and equipment maintenance and calibration records
- Quality Control testing data for reagents and chemicals

**Case Files Involving "No Match" Candidate Paperwork or Staff/Elimination DNA Profiles**

- If the case file contains "no match" candidate match paperwork, the "no match" candidate profile shall be redacted by the PDTC.
- If the case file contains a match to an elimination DNA profile belonging to a past or present employee, the case file may be sent with the past or present employee's DNA profile redacted by the PDTC. If the requestor requires the redacted information then a court order providing protection of the elimination DNA profile shall be sought prior to release of the documentation.
- If the case file contains a match to an elimination DNA profile, not belonging to a past or present employee, the case file may be sent with the elimination DNA profile, but the name of the person redacted by the PDTC. If the requestor requires the redacted information then a court order providing protection of the elimination DNA profile and the name of the contributor shall be sought prior to release of the documentation.
- If a case file request required redaction of "no match" candidate paperwork or staff/elimination names and/or profiles, the following steps will be followed:
  - Scientist shall notify their supervisor, lab manager, PDTC, and CODIS Manager of the discovery request. The DNA Technical Leader can also be notified if appropriate.
  - The lab manager or CODIS Manager (or designee) shall consult with the Assistant Attorney General as soon as practicable.
  - Scientist shall notify the prosecutor and defense attorney that a copy of the redacted information will be released by the PDTC upon receipt of a court order providing protection of the elimination DNA profile and/or name.
  - If the elimination DNA profile is from a current WSP employee, the lab manager (or designee) shall provide notice to the affected employee prior to the release of their DNA profile.

Documentation associated with the release of a match to an elimination DNA profile (e.g. protective court order, notice to employee) shall be retained in the case file.

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## REVIEW

See the WSP CLD Quality/Operations Manual for a full description of Review procedures.

In addition to the Review procedures outlined in the WSP CLD Quality/Operations Manual, a qualified person performing a DNA Casework review (typically at the administrative review level) shall also review the chain of custody of item(s) for that case. The reviewer shall access the LIMS program to verify that the scientist had possession of the item(s). The chain of custody current to the time of review need only be reviewed (may be incomplete). This chain of custody review shall be documented on the review checklist within the case file.

Refer to the WSP Convicted Offender/CODIS Standard Operating Procedures Manual for information regarding the verification and resolution of database matches.

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## PROFICIENCY TESTING

Participation in a proficiency testing program is a major element of the Washington State Patrol CLD Quality Program. Regular proficiency testing is a critical element in the DNA Analysis QA Program. It is used to demonstrate the quality performance of the DNA functional area (FA) and its staff, as well as assuring that the testing procedure is working properly.

### OPEN PROFICIENCY TESTING

The DNA FA participates in open proficiency testing programs with samples provided by outside organizations (such as Collaborative Testing Services or Orchid Cellmark).

### PERSONNEL

All staff members in the DNA FA who are involved in the serology testing and DNA typing of samples from criminal cases or samples received from the convicted offender program, are required to complete proficiency testing on a semi-annual (or 2x) basis each year. Newly qualified forensic scientists shall enter the external proficiency testing program within six months of the date of their qualification. Other personnel designated by the DNA technical leader to technically review outsourced DNA cases or convicted offender samples are also required to participate in the external proficiency-test program.

### FREQUENCY

Each DNA analyst and other personnel designated by the DNA technical leader (Standards & Accountability) shall undergo external proficiency testing twice a year, one between January 1st and June 30th and the other between July 1st and December 31st, with the interval between the two being 4 to 8 months. The designated date for proficiency test tracking for each lab is as follows:

- Seattle – received date
- Tacoma – submitted date (results faxed to manufacturer)
- Marysville – submitted date (results faxed to manufacturer)
- Spokane – due date
- Vancouver – due date
- CODIS – received date
- Standards and Accountability – received date

### TECHNOLOGY

The typing of all CODIS core loci is required for each proficiency test. For forensic scientists approved for YSTR typing, the proficiency testing for YSTRs must be done on a semi-annual basis. Technical reviewers for outsourced DNA cases or convicted offender samples must be qualified, or previously qualified, in the technology, platform, and typing amplification test kit used to generate the data.

### METHODOLOGY

Forensic scientists qualified in both automated and manual methods at minimum will perform alternate analysis of proficiency tests between both analytical processes.

### SEROLOGY SCREENING

For those individuals involved in Serology Screening for biological evidence and preparation of cell pellets for DNA analysis, the proficiency test will involve teaming with DNA analysts twice a year. Individuals

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involved in Serology Screening for biological evidence only will undergo annual external proficiency testing.

## SPECIMENS

For those individuals responsible for DNA typing of convicted offender samples, the proficiency samples will consist of dried bloodstains or buccal samples. For those individuals involved in DNA analysis and/or Serology Screening on criminal casework, the proficiency samples will consist of dried specimens of blood and/or other physiological fluids either singly or in mixtures. For other individuals designated only for outsourced case technical review, the proficiency samples will consist of electronic data of analysis results from dried specimens of blood and/or other physiological fluids either singly or in mixtures. These proficiency samples will normally be presented as a case situation with specific questions to be answered.

## SAMPLE PREPARATION, STORAGE, AND DISTRIBUTION

All internally developed proficiency test specimens should be uniformly prepared using materials and methods that ensure their integrity and identity. Each set and specimen must be labeled with a unique identifier.

Each proficiency test will be treated as a laboratory case and as such, will have an associated RFLE and assigned a unique laboratory number. Samples will be stored in an appropriate manner pending analysis. Proficiency tests will be assigned to individuals in the DNA section by the section supervisor. Proficiency tests will be assigned to individuals in the CODIS laboratory by the CODIS manager. Proficiency tests will be assigned to others designated only for outsourced case technical review by the DNA technical leader.

## DOCUMENTATION OF PROFICIENCY TEST RESULTS

The analyst will, without assistance and as appropriate to their role

- Conduct analysis.
- Interpret analytical data.
- Form conclusions (as appropriate).
- Write a report/fill in the proficiency forms and answer questions on the proficiency forms.

If an examiner has questions or requires assistance, the immediate supervisor should be contacted. The proficiency test case file should include the same information as is included with a casework file or convicted offender file, including electronic data. Outsourced case technical reviewer proficiency test case files will have the original electronic data DVD plus the reference sample form, sample analysis form, mixture analysis form(s) as appropriate plus a printed copy of the results and answers submitted electronically.

The proficiency test results shall be added to the proficiency test case file. Records of discrepancies between the test results as well as corrective actions taken shall be documented and maintained in the proficiency test case file. The completed proficiency test case file will be maintained in each lab.

## REVIEW AND REPORTING OF PROFICIENCY TEST RESULTS

The case file will undergo a technical peer review by a qualified analyst. An administrative review will also be completed by someone other than the individual being tested. Upon completion of a proficiency test, the case file will be returned to the appropriate supervisor, who will ensure that all necessary reporting forms have been completed.

A copy of the required reporting forms will be sent to the organization providing the test materials.

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When test results are available from the manufacturer, the CLD Quality Process Manager will review all test materials, determine whether the results reported by the analyst are correct and send out a report. The DNA Technical Leader or designee also reviews the CTS Manufacturer's Information Report relative to the results reported by the DNA analyst to assist the Quality Process Manager. The CLD Quality Process Manager will promptly notify the employee taking the test of the results, and a written summary of the results will be included in the file.

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## NON-CONFORMING WORK

The policies and procedures related to non-conforming work and corrective actions are outlined in the WSP CLD Quality/Operations Manual. The Remedy Nonconformance Tracking Program (RNTP) will be used to log all non-conforming work and corrective actions.

Non-conforming work is defined by the CLD Quality/Operations Manual: There are two levels of non-conforming work: substantive (as defined in the CLD QOM) and quality variance.

Quality variance incidents in the DNA functional area include but are not limited to: contamination (confirmed or unconfirmed), sample switching, inadvertent sample loss (due to dropping or spilling), and sample mixing. The analyst shall document the incident in the case file(s) and notify their section supervisor. Quality variance incidents will be documented. If identified as a finding during an audit, the audit document can be used and the finding is entered into RNTP. If identified during a testimony evaluation the testimony evaluation form can be used and the incident is entered into RNTP. Quality variances identified otherwise will be documented using the RNTP. Quality variance entries shall include the case number(s); incident date; the type of incident; if contamination, the deduced source of the DNA or the interpretable allele calls; description of circumstances; whether noted in the report or not; action(s) taken; and the analyst and supervisor names.-The DNA Technical Leader is notified of quality variance entries in RNTP for system-wide monitoring.

The DNA Technical Leader, or designee, will review all reported quality variances and assess the severity. For those events determined to be substantive non-conformances, the CLD QOM policy regarding the Corrective Action Process and Non-Conforming work will be followed. All other events will be treated as minor variances and monitored, as appropriate. Should multiple minor events occur for a single individual or multiple similar minor events occur for a laboratory or across a laboratory system, the group of instances may rise to the level of a substantive non-conformance. Supervisors, or their designee, shall review their lab's quality variances quarterly and report the result to their staff either via email or at a unit meeting. The DNA Technical Leader shall also be notified of the quarterly variances summary via email.

If an event appears potentially substantive, where a formal Corrective Action would be required, the DNA Technical Leader will be notified as soon as practicable.

If no results can be reported due to a quality variance incident, the final laboratory report will indicate the reason(s) why.

Significant contamination incidents shall be noted in a case report. This would include all reportable DNA profiles suspected of being introduced to evidence samples or control samples while conducting lab procedures. Refer to the WSP Crime Laboratory STR Analysis Procedures Manual for suggested wording of reports.

Unconfirmed contamination based on data below the allele reporting threshold is assessed by the DNA analyst, peer reviewer and supervisor on a case-by-case basis for plausibility of trace DNA contamination, potential for impact on DNA profile interpretation and as to whether it is sufficiently significant to be noted in the report.

Refer to Extraneous DNA Guidelines in Appendix 1 for assistance in casework contamination troubleshooting. For CODIS analysts, refer to Appendix 2 for assistance in contamination troubleshooting. If an extraneous profile is attributable to an unknown source, then attach the profile to the quality variance entry in RNTP.

Corrective actions involving DNA analysis shall not be implemented without the documented approval of the DNA Technical Leader.

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## AUDITS

Audits are an important aspect of the DNA FA's QA Program. They are an independent review conducted to compare the DNA FA's performance with a standard for that performance.

The DNA and CODIS laboratories will be audited annually with an external audit in alternating years. The audit will be conducted in accordance with the FBI DNA QAS document. The annual audits occur every calendar year and will be at least 6 months and no more than 18 months apart.

### OBJECTIVES

There are two primary objectives of an audit:

1. To provide management with an evaluation of the DNA FA's performance in meeting its quality assurance policies and objectives.
2. To identify the areas in which the DNA FA performance may be improved.

### TYPES OF DNA FUNCTIONAL AREA AUDITS

#### Audits of the DNA FA

The DNA Technical Leader conducts and documents an annual review of the DNA Quality Assurance Program.

On a biennial basis, each DNA laboratory undergoes an external audit designed to determine the extent to which the section meets the FBI DNA Quality Assurance Audit document.

The audit is conducted by a team comprised of at least two individuals from an external agency one of which must have successfully completed the FBI DNA Auditor Workshop and is or has been qualified in the specific DNA technology used in the CLD DNA laboratory to be audited.

A record (including a summary report prepared by the DNA Technical Leader) of each external audit will be maintained and include the date of the inspection, the names of the members of the inspection team, the findings and problems identified by the team, and remedial action taken to resolve existing problems. Any findings of non-conforming work will be addressed through corrective action processes.

On alternative years, each DNA laboratory undergoes an internal audit designed to determine the extent to which the section meets the FBI DNA Quality Assurance Audit document.

The audit is conducted under the direction of the DNA Technical Leader by at least one qualified auditor and one qualified (or previous qualified) DNA Analyst from another CLD laboratory and/or the DNA Technical Leader. The CODIS laboratory will have at least one qualified database analyst in the audit team.

A record (including a summary report prepared by the DNA Technical Leader) of each internal audit will be maintained and include the date of the inspection, the names of the members of the inspection team, the findings and problems identified by the team, and remedial action taken to resolve existing problems. Any findings of non-conforming work will be addressed through corrective action processes.

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The annual DNA audits (both internal and external) will be incorporated in the FLSB quality internal audits and Management System Reviews.

#### FLSB Management System Review and Internal Quality Audits

The annual internal quality audit and Management System Review (MSR) are reviews of the laboratory's management and quality systems and testing activities to ensure continuing suitability and effectiveness. These reviews will be used as tools to introduce necessary changes or improvements by management.

As a part of the FLSB, the DNA section and its activities will be subject to the annual MSR to ensure the continued suitability and effectiveness of the quality system and laboratory operation, compliance with established FLSB policies, current accrediting body requirements, any supplemental document requirements, the FBI DNA Quality Assurance Standards, and applicable WSP policies, rules and regulations.

The procedures for the annual internal quality audit and MSR are outlined in the CLD Quality/Operations Manual.

#### **ANAB INSPECTION**

Each laboratory of the Crime Laboratory Division is accredited by ANAB. As part of the accreditation process, all sections of each laboratory are inspected every four years to ensure that current accreditation requirements are being met. An ANAB inspection fulfills the biennial external audit requirement.

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## SAFETY

Refer to the WSP CLD Quality/Operations Manual, section 22 Health and Safety, the WSP Safety and Wellness Manual Chapter 13 – Hazardous Chemical Communication Plan and the CLD Safety Manual for information on safety planning.

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## OUTSOURCING

When external laboratories are contracted to perform DNA typing for WSP Crime Laboratories, the external laboratories will be subject to the policies and procedures outlined in the WSP CLD Quality/Operations Manual, section 19. The vendor laboratory shall comply with the FBI DNA Quality Assurance Standards.

Refer to the appropriate WSP STR DNA Analysis Procedures Manual and the Convicted Offender/CODIS Standard Operating Procedures for technical review and upload procedures regarding vendor laboratory DNA data.

To establish an Outsourcing Contract the following steps are taken:

- Acquire the vendor's Analysis and Quality Assurance procedures, validation reports, the last external DNA audit document, accreditation certificate.
- Document the technical review by the DNA Technical Leader of analysis and quality assurance procedures, last external DNA audit document, accreditation certificate and proficiency test records
- Document WSPCL DNA Technical Leader approval of outsourcing contract technical specifications prior to issuance of contract.
- Determine who will perform the case file reviews
- Designate a lead case file reviewer as the point person and project coordinator
- Design and implement a technical review SOP for the contracted case files, data interpretations and conclusions
- Provide training to case reviewers on vendor file organization and review process and on any major technical differences between the WSP CL and the vendor laboratory
- Perform a yearly technical onsite visit\* of the vendor lab and assess quality assurance performance (obtain current audit documents and check for corrective actions), resolve technical issues and assess for critical changes in work environment.
- WSP CL Forensic Scientists will provide Hit confirmation reports however the confirmatory reference sample analysis and subsequent report will be done by the vendor lab.
- Vendor laboratory Forensic Scientists are responsible for the case file report and any testimony for cases that proceed to court in the future.

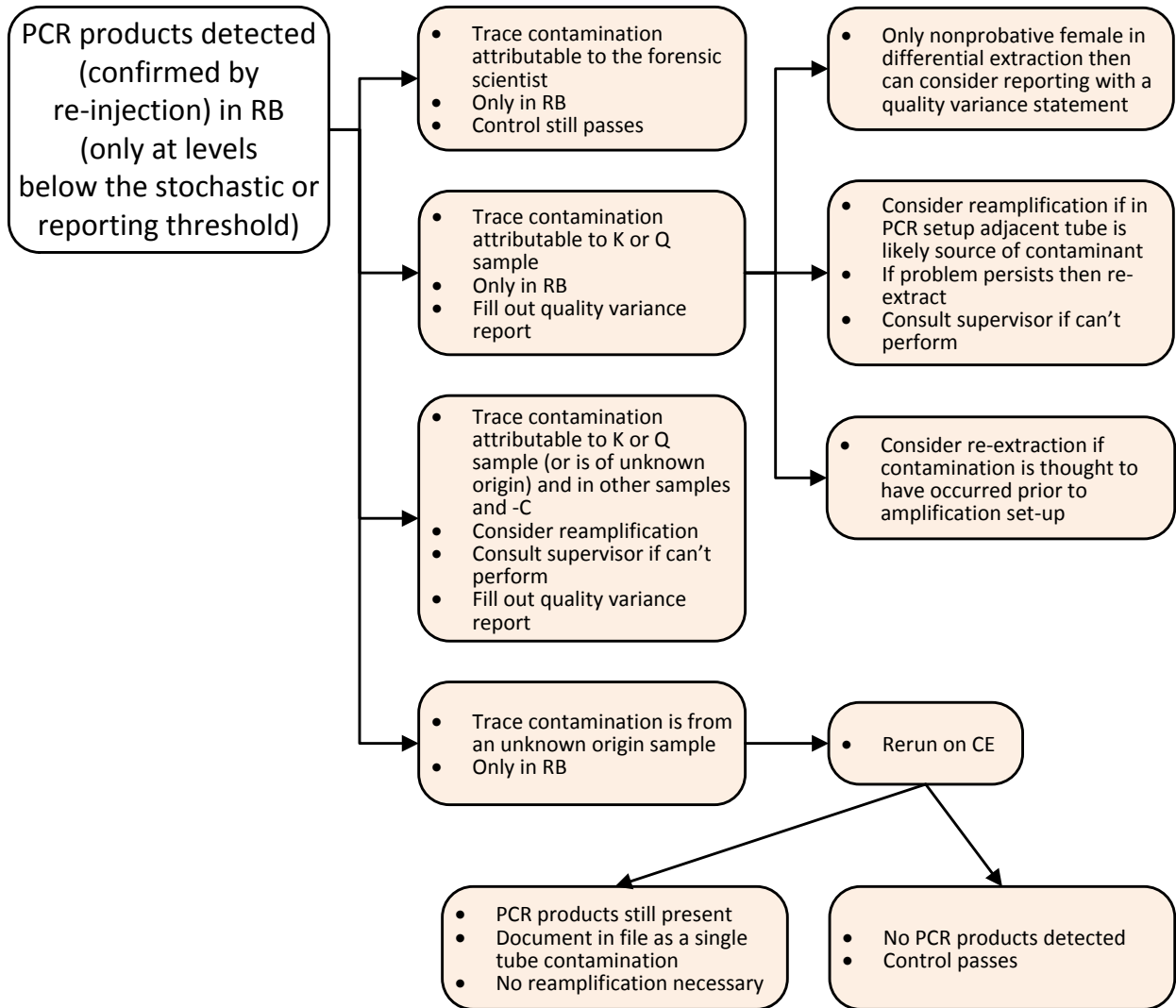
\*Note - In addition to the technical leader (or designee) performing an on-site visit, the DNA Technical Leader may elect to accept information/documentation generated from an on-site visit conducted of the vendor laboratory by an NDIS laboratory using the same technology, platform, and typing amplification test kit as long as it was conducted within the past twelve months. Alternatively, the DNA Technical Leader may accept an on-site visit conducted by a designated FBI employee. Documentation shall include review and approval of the on-site visit, the date the on-site visit was performed, a summary of the visit, and the documentation of the personnel who performed the on-site visit.



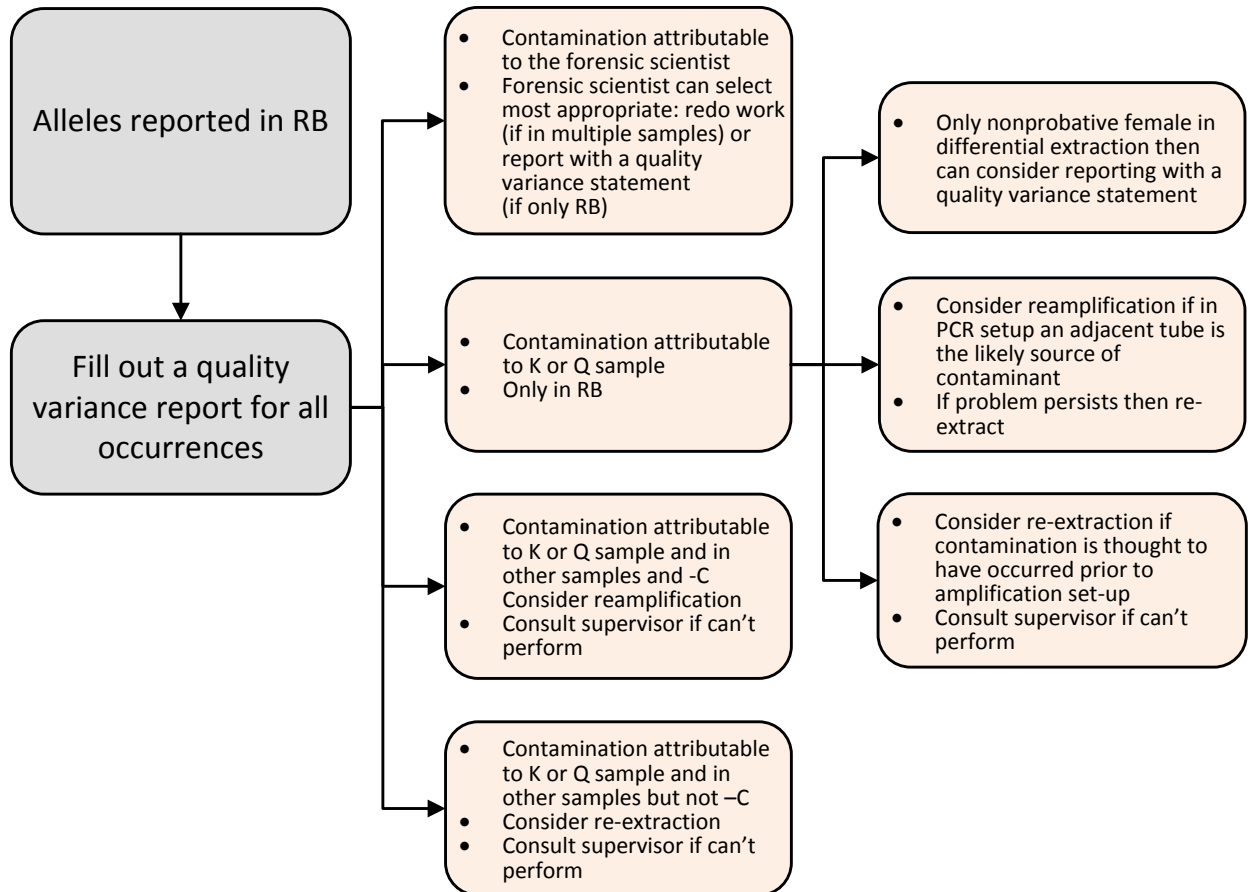
## APPENDIX I – EXTRANEOUS DNA GUIDELINES

### APPENDIX I – EXTRANEOUS DNA GUIDELINES

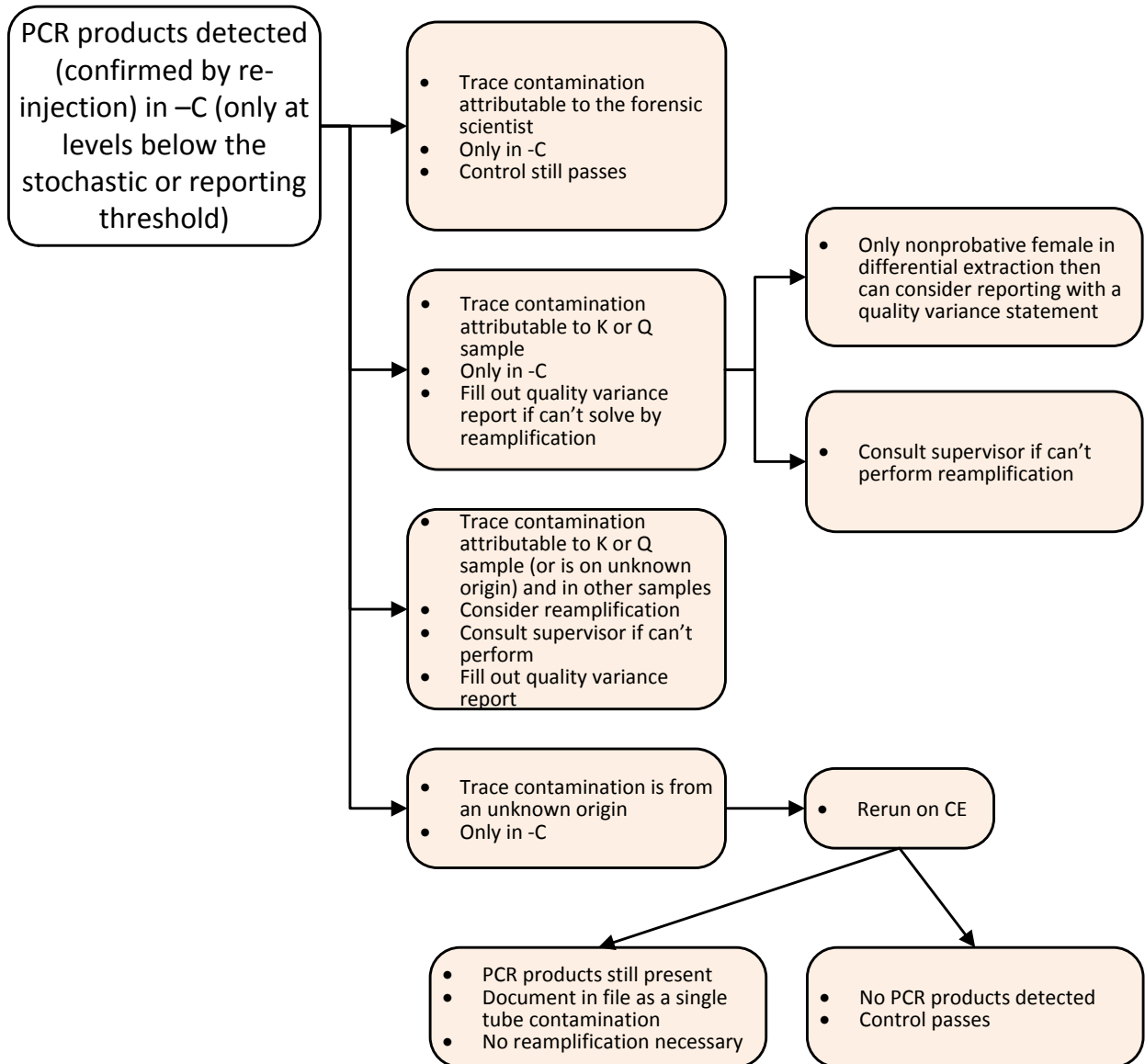
See the CODIS Procedures Manual for the follow-up procedure when the extraneous DNA profile contributor is unidentified.



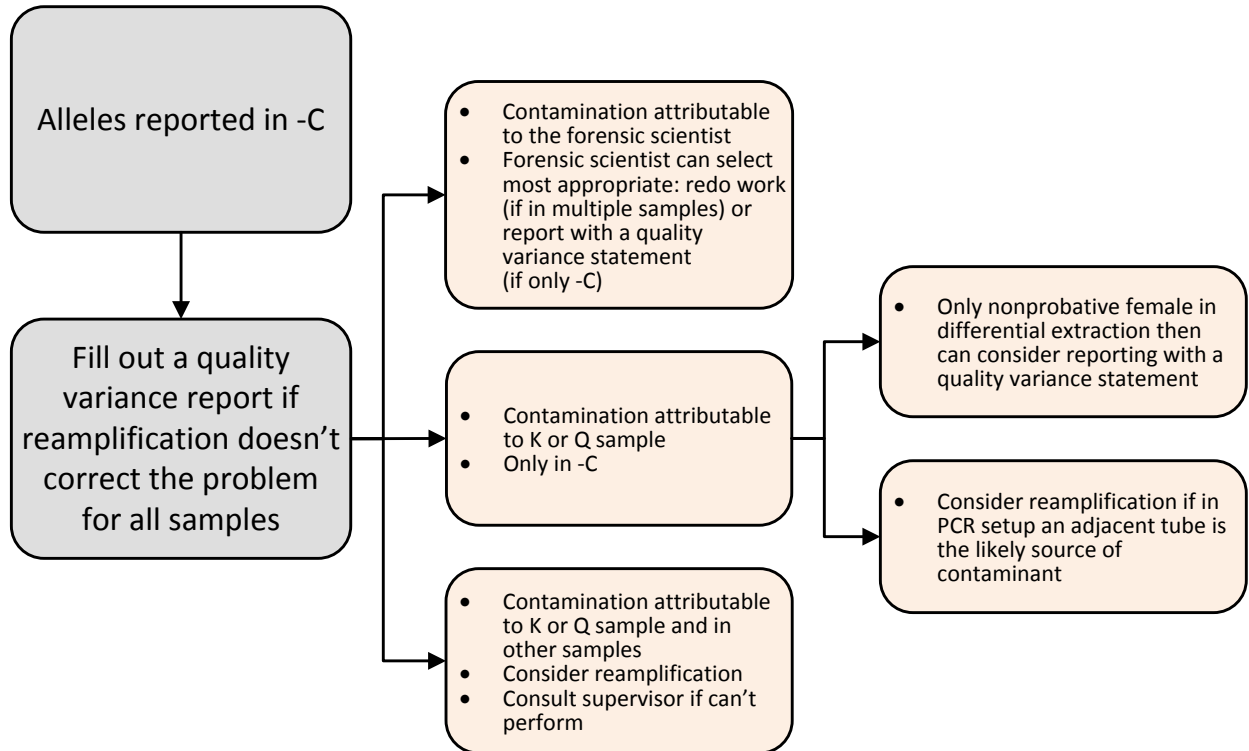
See the CODIS Procedures Manual for the follow-up procedure when the extraneous DNA profile contributor is unidentified.



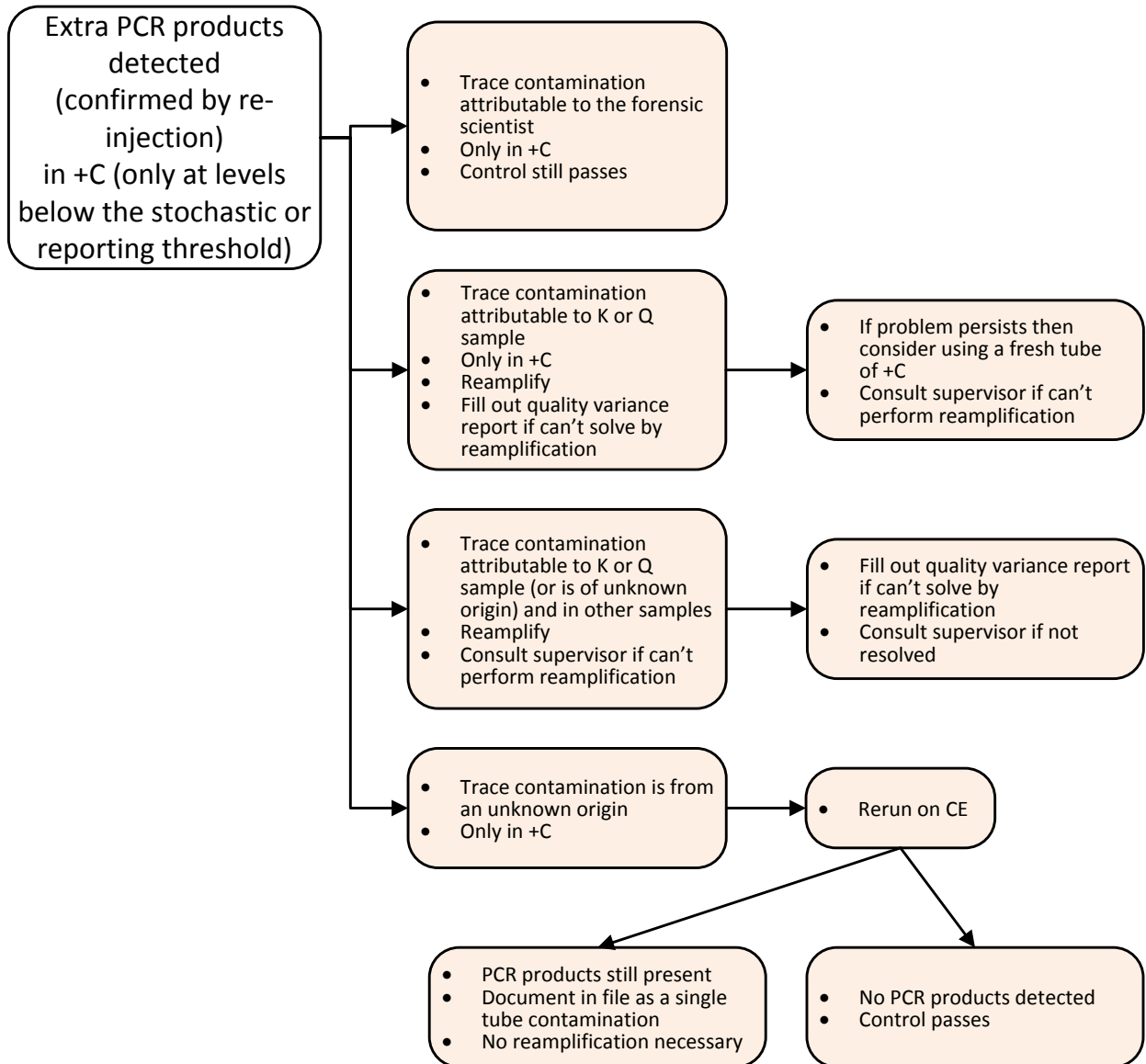
See the CODIS Procedures Manual for the follow-up procedure when the extraneous DNA profile contributor is unidentified.



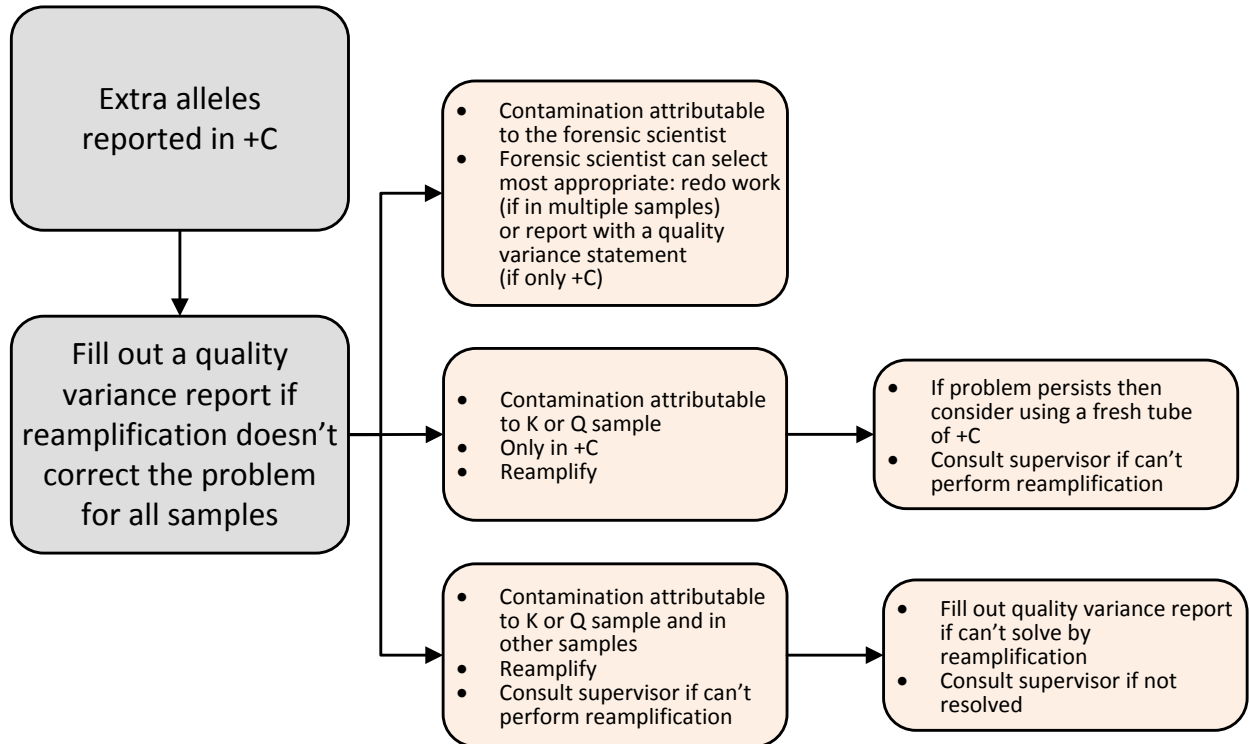
See the CODIS Procedures Manual for the follow-up procedure when the extraneous DNA profile contributor is unidentified.

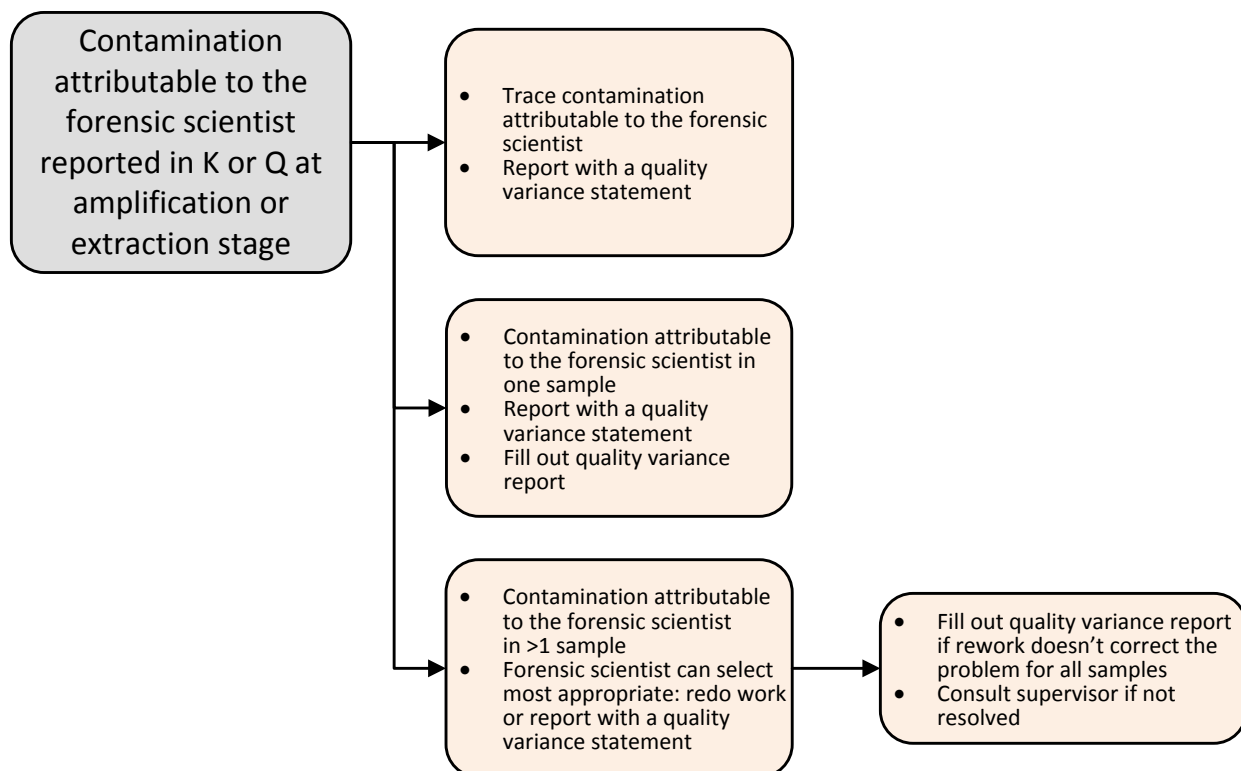


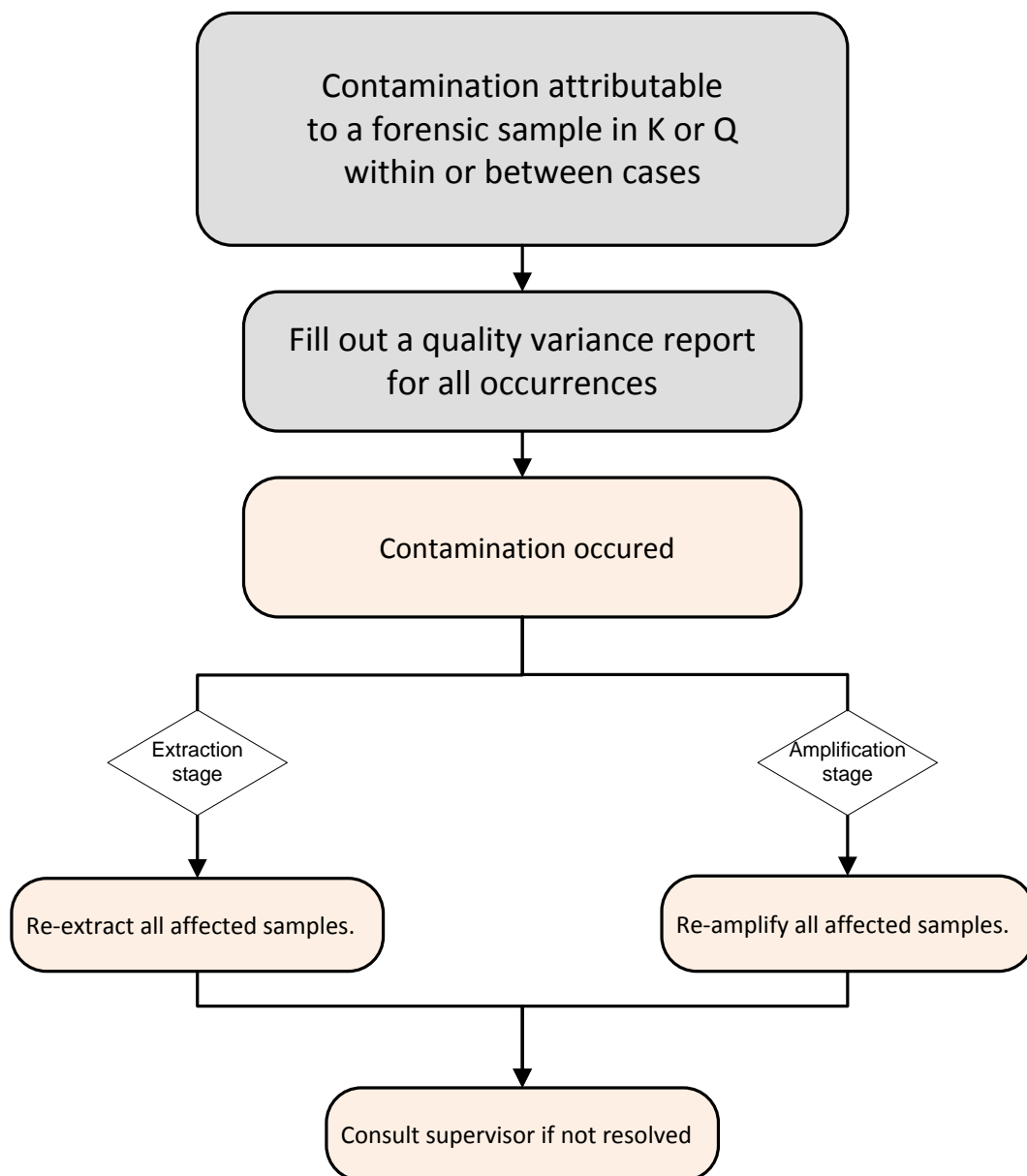
See the CODIS Procedures Manual for the follow-up procedure when the extraneous DNA profile contributor is unidentified.



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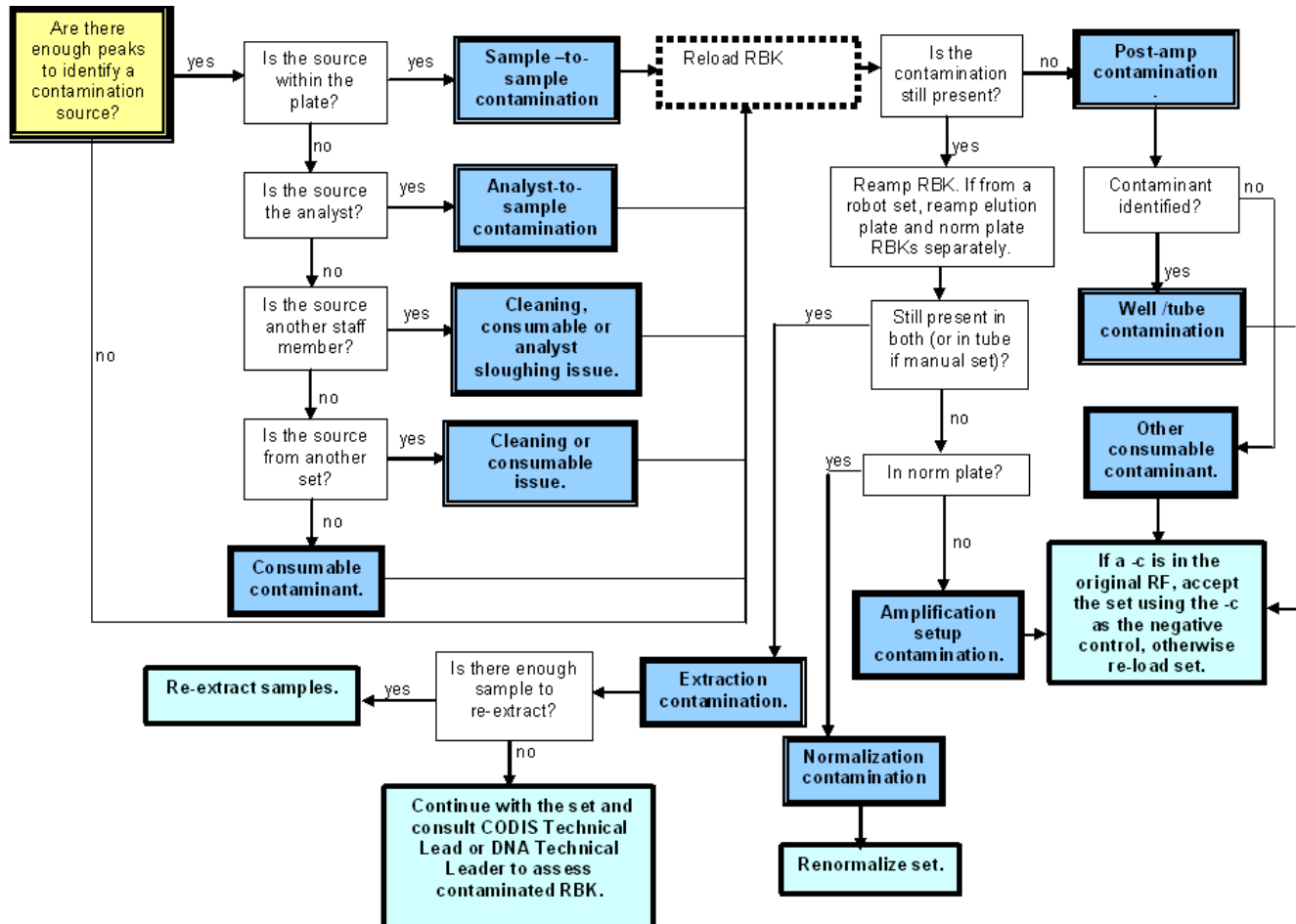




## APPENDIX II – EXTRANEOUS DNA GUIDELINES - CODIS

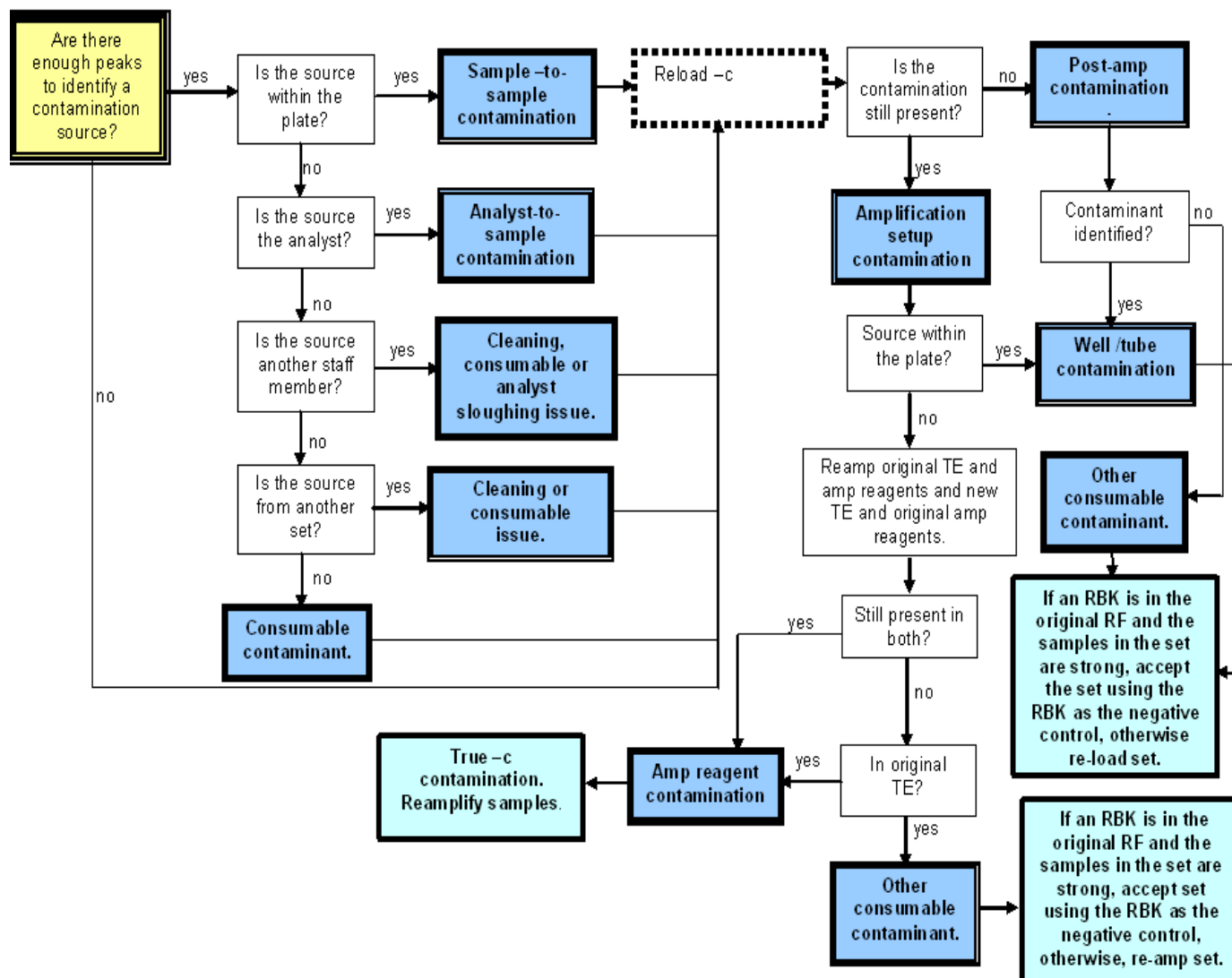
### Contamination in RBK only

A quality variance log entry should be filled out for all instances of RBK contamination.  
See the CODIS Procedures Manual for the follow-up procedure when the contamination is unidentified.



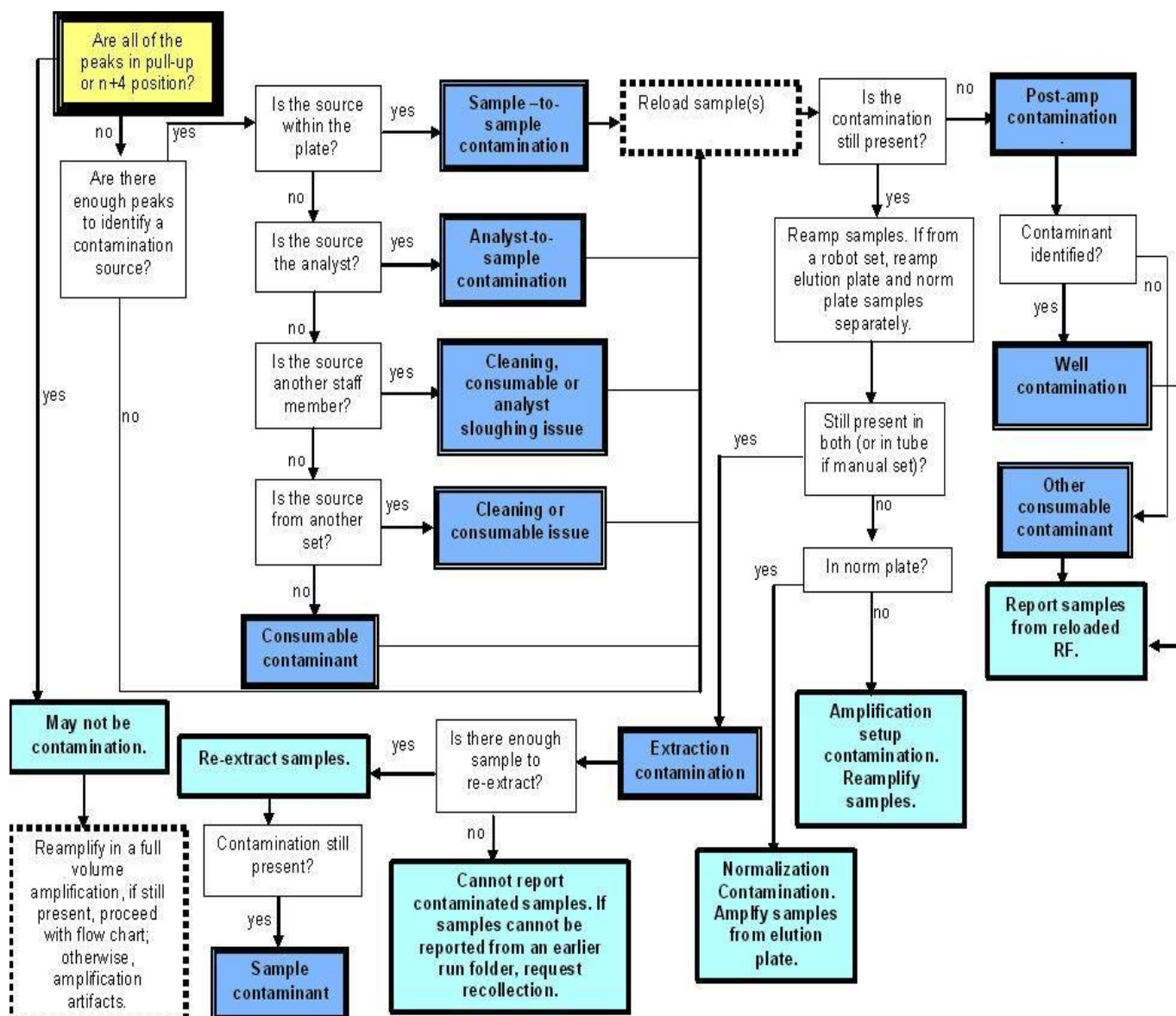
## Contamination in –c only

A quality variance log entry should be filled out for all instances of –c contamination.  
See the CODIS Procedures Manual for the follow-up procedure when the contamination is unidentified.



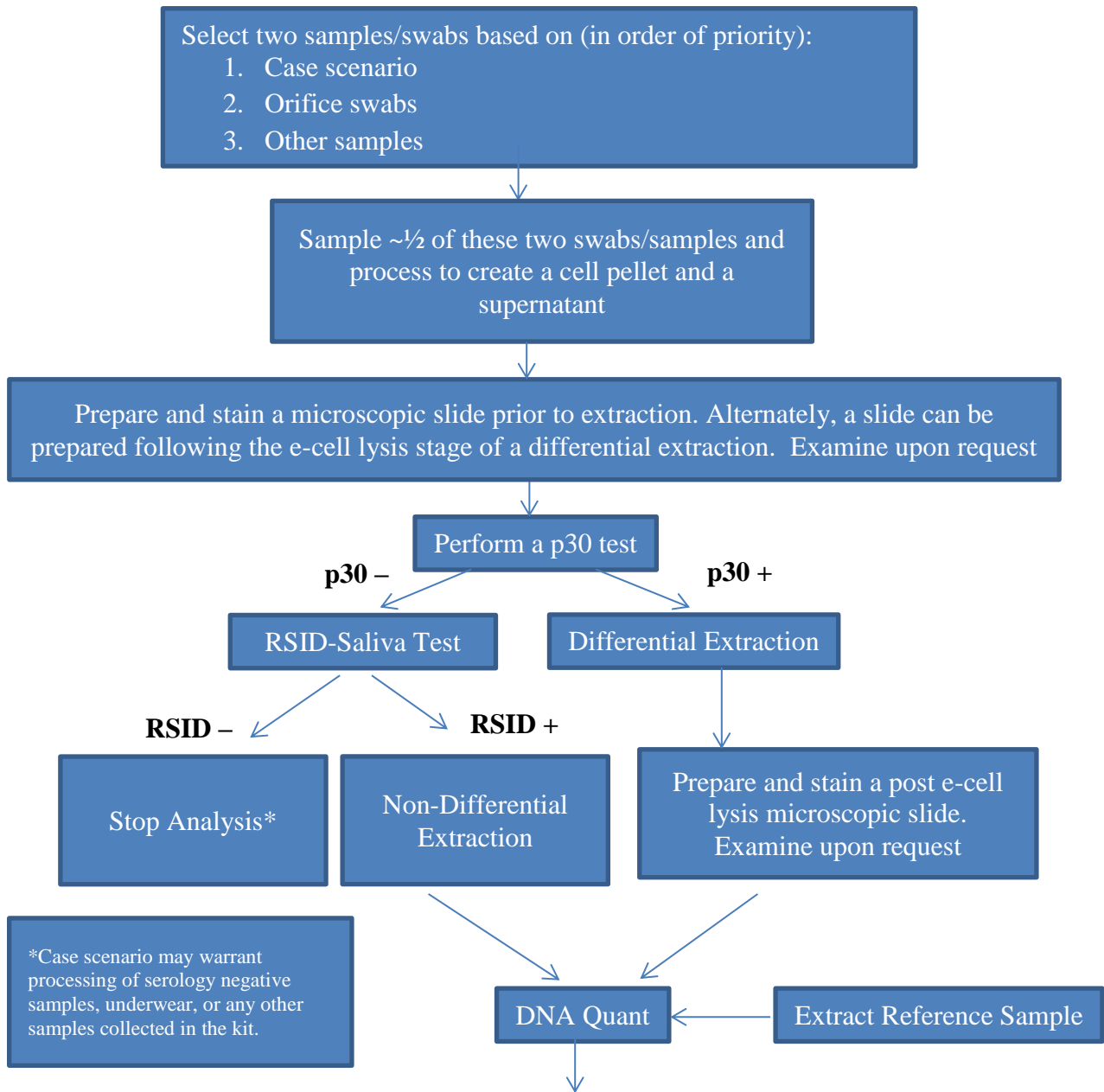
## Contamination in a sample(s)

A quality variance log entry should be filled out for all instances of sample contamination. See the CODIS Procedures Manual for the follow-up procedure when the contamination is unidentified.



## APPENDIX III – RAPID APPROACH TO SAK2 CASES FLOW CHART

### SAK-2 Rapid Processing Proposal



Auto/Y Ratio	Limited Male DNA	Substantial Male DNA
<b>Suitable</b>	Amplify or Extract Add'l Sample	Amplify
<b>Unsuitable</b>	Stop Analysis	Stop Analysis

## REVISIONS

Complete Revision	version May 2004
Analytical Procedures	version Feb 2005
Proficiency Testing	version April 2005
Evidence Control	version April 2006
Table of Contents	version November 2006
Goals and Objectives	version November 2006
Organization and Management	version November 2006
Personnel Qualifications & Training	version November 2006
Methods Validation	version November 2006
Analytical Procedures	version November 2006
Proficiency Testing	version November 2006
Discrepancies	version November 2006
Revisions	version November 2006
Organization and Management	version April 2007
Personnel Qualifications & Training	version April 2007
Facilities	version April 2007
Analytical Procedures	version April 2007
Equipment Calibration & Maintenance	version April 2007
Proficiency Testing	version April 2007
Discrepancies	version April 2007
Review	version April 2007
Audits	version April 2007
Evidence Control	version June 2007
New Manual	version Sept 2008
Analytical Procedures	version Jan 2009
Outsourcing	version Jan 2009
Technical Review	version Jan 2009
DNA and Analytical Procedures	version Jan 2009
Extraneous DNA Guidelines	version Jan 2009
Casework Evidence and Sample Control	version Jan 2009
Goals and Objectives (identify QA Manager, CLD Manual	version Aug 2009
Proficiency Testing	version Aug 2009
Equipment Calibration and Maintenance	version Aug 2009
DNA Functional Area Audits	version Aug 2009
Continuing Education	version Aug 2009
Alleles Tables Option	version Aug 2009
Comparison to Known Standards, Data Handling/Storage	version Aug 2009
Levels of Authority	version Aug 2009
Organization and Management(Reference to CLD Quality Manual)	version Aug 2009